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EXAMINER	
BHAT, NARAYAN KAMESHWAR	
ART UNIT	PAPER NUMBER
1634	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,162	BOSNES, MARIE	
	Examiner	Art Unit	
	NARAYAN K. BHAT	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 28-32* is/are pending in the application.

4a) Of the above claim(s) *30-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 28-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

1. This office action is written in reply to applicant's correspondence filed February 11, 2008. Claim 1 was amended and claims 26-27 were cancelled. Applicant's amendments requiring nucleic acid components contained in sample become bound to the solid support in a sequence independent manner necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

2. Claims 1-25 and 28-32 are pending in this application and are under prosecution.

3. Claims 30-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 11, 2007.

4. Claims 1-25 and 28-29 are under prosecution.

Amendments to the Claim

5. Amendments to the claim 1 have been reviewed and entered.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-20, 22-25 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Laugharn et al (USPN 6,120,985 issued Sep. 19, 2000).

Regarding claim 1, Laugharn et al teaches a method if isolating nucleic acid and proteins from each other in a sample and the method include providing a solid phase material in a cartridge (Fig. 1, cartridge # 10, solid phase material # 18, column 18, lines 30-34) and further teaches that cartridge include multiple compartments containing different solid phase material (column 19, lines 27-31), thus teaching a plurality of solid supports.

Laugharn et al also teaches the solid phase material comprises anion exchange resins to which nucleic acids binds tightly (column 9, lines 55-64), thus encompassing nucleic acid components bind to the solid support in a sequence independent manner. Laugharn et al further teaches that the positively charged proteins are captured by the solid phase comprising cation exchange resin (column 19, lines 66-67, column 20, lines 1-3). Laugharn et al further teaches that proteins bound to the solid phase are eluted at lower pressure than the nucleic acids which bind more tightly to the solid phase, thus teaching that protein components contained in the sample binds to a solid support having a surface capable of effecting chromatographic interaction (column 9, lines 65-67 and column 10, lines 1-13).

Teachings of Laugharn that the nucleic acid binds solid phase comprising anion exchange resin and proteins bind to cation exchange resin encompasses nucleic acid components and protein components are bound to distinct solid supports as claimed.

Regarding claim 2, Laugharn et al teaches an embodiment wherein differential pressure is applied to elute RNA and then chromosomal DNA from the solid support (column 3, lines 42-65), thus teaching DNA and RNA were bound to the same solid support prior to elution.

Regarding claims 3 and 4, Laugharn et al teaches an embodiment wherein DNA is bound to an electrode, i.e., solid support (Fig. 3, # 170) and RNA is bound to another electrode, i.e., solid support (Fig. 3, # 140, column 21, lines 31-57), thus teaching solid supports are distinct.

Regarding claim 5, Laugharn et al teaches that the DNA, RNA and protein are isolated from the same sample (Example 13, column 32 lines 21-67, column 33, lines 1-16).

Regarding claim 6, Laugharn et al teaches that the RNA is mRNA (Example 5, column 27, line 56).

Regarding claim 7, Laugharn et al teaches that the DNA is genomic (Example 11, column 30, line 59).

Regarding claim 8, Laugharn et al teaches that the total RNA (Example 4, column 26, line 62) and/or the total DNA is isolated (Example 13, column 32 lines 21-67, column 33, lines 1-16).

Regarding claim 9, Laugharn et al teaches that the total nucleic acid component is isolated (column 9, lines 55-63).

Regarding claim 10, Laugharn et al teaches that the total protein component is isolated (column 9, lines 55-57).

Regarding claim 11, Laugharn et al teaches that the sample is a tumor biopsy sample, plant and biological fluids (column 3, lines 42-46), which is a clinical or biological or environmental sample.

Regarding claim 12, Laugharn et al teaches that prior to contacting said sample with said solid supports, the sample is subjected to a cell lysis with elevated pressure and releasing the cell contents in to buffer solution that is, a preliminary treatment step to free the nucleic acid and/or protein components from structures or entities in which they may be contained (column 5, lines 30-54).

Regarding claims 13 and 14, Laugharn et al teaches the isolation of leukocytes from blood, i.e., particular cell populations (Example 7, column 29, lines 2-12), thus teaching prior to contacting solid supports, the sample is subjected to a cell isolation procedure for isolating specific cell type.

Regarding claim 15, Laugharn et al teaches that the cells are lysed with GITC containing buffer (Example 7, column 29, lines 10-15), thus teaching sample is subjected to a cell lysis step prior to contacting said sample with said solid supports.

Regarding claim 16, Laugharn et al teaches an assay that includes isolation of blood cells and treatment of blood cells in vitro with red blood cell lysis solution to lyse the red blood cells and to obtain leukocyte cells (Example 7, column 29, lines 2-10). The manipulation of leukocyte cells in vitro by red blood cell lysis solution is interpreted broadly to encompass isolated cells from the sample are subjected to an in vitro modification procedure prior to the cell lysis step.

Regarding claim 17, Laugharn et al teaches that the same cell lysate is used for nucleic acid and protein isolation thus teaching that the sample is not divided at any stage of the method (Example 13, column 32, lines 21-67, column 33, lines 1-16).

Regarding claim 18, Laugharn et al teaches an embodiment wherein different aliquots of the cells are used to isolate nucleic acids using either high pressure or detergent to lyse the cells (Example 16, column33, lines 57-67, column 34, lines 1-49), thus teaching the sample is divided after cell isolation.

Regarding claim 19, Laugharn et al teaches that the sample is lysed and cellular contents are contacted with the probe on the solid supports simultaneously (pg. 16, paragraph 5).

Regarding claim 20, Laugharn et al teaches the sequential elution of protein component from the nucleic acid component at 10,000 psi pressure (Example 13, column 32, lines 21-35 and 59-67, column 33,lines 1-8, first step of the claim), which is interpreted broadly as isolating proteins. Laugharn et al also teaches in a second step isolating the RNA at 23,000 psi and in a third step isolating the DNA at 45,000 psi (Example 13, column 32, lines 21-67, column 33, lines 1-16), which meet the limitation of claim, because steps may be performed in any order.

Regarding claim 22, Laugharn et al teaches that the DNA is isolated on a support using cells lysed with detergent (Example 11, column 30, lines 59-67).

Regarding claim 23, Laugharn et al teaches different embodiments, wherein cell lysis and nucleic acid binding to a solid support occur simultaneously (Example 7, column 28, lines 59-67) or concomitantly (Example 13).

Regarding claims 24 and 25, Laugharn et al teaches that the RNA is isolated using oligo-dT column (column 10, lines 24-25) or oligo-dT attached to an electrode (Fig. 3, # 140, column 21, lines 31-34), which is capable of binding to mRNA (Example 5).

Regarding claim 28, Laugharn et al teaches a plurality of solid phase materials, i.e., solid supports (column 19, lines 27-31) and further teaches that solid supports are particles (column 2, line 4-5).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 21and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laugharn et al (USPN 6,120,985 issued Sep. 19, 2000) in view of Smith et al (USPN 6,310,199 issued Oct. 30, 2001).

Claim 21 is dependent from claim 1. Claim 29 is dependent from claim 28, which is dependent from claim 1. Teachings of Laugharn et al regarding claim 1 are described previously in this office action.

Regarding claim 21, Laugharn teaches that support comprise ion exchange resins having a variety of groups on the surface but is silent about carboxyl groups

(column 2, lines 61-67 and column 3, lines 1-4). However, support comprising carboxyl groups on their surface was known in the art before the claimed invention was made as taught by Smith et al, who teaches a pH dependent ion exchange matrix covalently coupled to a solid support comprising surface carboxyl group (column 12, lines 33-53). Smith et al also teaches that the pH dependent ion exchange matrix comprising surface carboxyl functional group binds to the nucleic acids at a lower pH and nucleic acids are eluted at neutral pH (Abstract, column 13, lines 18-32). Smith et al also teaches that the nucleic acids isolation using pH dependent ion exchange matrix requires very few steps, without the use of hazardous chemicals, little or no salt for elution and the nucleic acids are used immediately without further extraction or isolation (Abstract).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the solid support in the biological material purification method of Laugharn et al with the carboxylated solid support of Smith et al with a reasonable expectation of success.

An artisan would have been motivated to modify the solid support in the biological material purification method of Laugharn et al with the expected benefit of using pH dependent ion exchange matrix comprising surface carboxyl groups for nucleic acid isolation requiring nucleic acids isolation using pH dependent ion exchange matrix requires very few steps, without the use of hazardous chemicals, little or no salt for elution and availability of nucleic acids for immediate use without further extraction or isolation as taught by Smith et al (Abstract), thus able to use pH gradients in addition to pressure gradients in the nucleic acid isolation method of Laugharn et al.

Regarding claim 29, Laugharn et al teaches that solid support comprises magnetic based separation (column 16, lines 51-58), but is silent about magnetic particles. However magnetic particles were known in the art before the claimed invention was made as taught by smith et al who teaches magnetic particles for nucleic acids and protein isolation (column 3, lines 20-23, column 11, lines 38-45). Smith et al also teaches magnetic particle based isolation is quick to use and do not require use of corrosive and hazardous chemicals (column 4, lines 24-27).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the solid support in the biological material purification method of Laugharn et al with the magnetic particles of Smith et al with a reasonable expectation of success.

An artisan would have been motivated to modify the solid support in the biological material purification method of Laugharn et al with the expected benefit of using magnetic particle based isolation method, which is quick to use and not requiring use of corrosive and hazardous chemicals as taught by Smith et al (column 4, lines 24-27).

10. Claims 1 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laugharn et al (USPN 6,120,985 issued Sep. 19, 2000) in view of Olsvik et al (WO 92/17609 published in Oct.15, 1992).

Claim 29 is dependent from claim 28, which is dependent from claim 1. Teachings of Laugharn et al regarding claims 1 and 28 are described previously in this office action.

Regarding claim 29, Laugharn et al teaches that solid support comprises magnetic based separation (column 16, lines 51-58), but is silent about magnetic particles. However magnetic particles were known in the art before the claimed invention was made as taught by Olsvik et al.

Olsvik et al teaches magnetic particles (pg. 4, paragraph 3) and further teaches derivatisation of the magnetic particles with binding partners to separate target cells and pathogenic contaminants from large volume and number of mixed cell populations for nucleic acid isolation and detection of pathogens by PCR (Fig. 1, Abstract, pg. 3, paragraph 2, pg. 6, paragraph 2).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the solid support in the biological material purification method of Laugharn et al with the magnetic bead solid support of Olsvik et al with a reasonable expectation of success.

An artisan would have been motivated to modify the solid support in the biological material purification method of Laugharn et al with the expected benefit of further modifying the magnetic bead support with binding partners to separate target cells and pathogenic contaminants from large volume and number of mixed cell populations for nucleic acid isolation and detection of pathogens by PCR as taught by Olsvik et al (Fig. 1, Abstract, pg. 3, paragraph 2, pg. 6, paragraph 2), thus having

enriched population of selected target cells for nucleic and protein isolation in the method of Laugharn et al for further expanding their utilities.

Response to Remarks from the Applicants

Claim Rejections under 35 U.S.C. § 102(b)

11. Applicant's arguments with respect to claims 1, 5-6, 11-13, 15-17, 19, 22-24, 26 and 28-29 have been considered but are moot in view of the new ground(s) of rejection necessitated by claim amendments (Remarks, pgs. 6-7).

Claim Rejections under 35 U.S.C. § 103(a)

12. Applicant's arguments under 103(a) rejections have been considered but are moot in view of the new ground(s) of rejection necessitated by claim amendments (Remarks, pgs. 7-10).

Conclusion

13. No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Narayan K. Bhat/

Examiner, Art Unit 1634

Narayan K. Bhat, Ph. D.

/BJ Forman/

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